UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION This document relates to: *The Blackfeet Tribe of the Blackfeet Indian Reservation v. Amerisource Bergen Drug Corporation, et al.* Case No. 1:18-op-45749	MDL No. 2804 Case No. 17-md-2804 Hon. Dan Aaron Polster

PARTIAL OBJECTION OF THE GENERIC MANUFACTURERS TO THE REPORT AND RECOMMENDATION OF THE MAGISTRATE JUDGE ON THEIR MOTION TO DISMISS

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INTRODUCTION

Pursuant to Fed. R. Civ. P. 72(b)(2), Defendants Watson Laboratories, Inc., Actavis Pharma, Inc., Actavis LLC, Par Pharmaceutical, Inc., and Par Pharmaceutical Companies, Inc. (collectively, the "Generic Manufacturers") object in part to the magistrate judge's Report and Recommendation (the "Report" or "R&R") on the Generic Manufacturers' Motion to Dismiss (the "Motion").[1] The Report properly recognizes that false marketing claims—based upon something other than affirmative misrepresentations—against the Generic Manufacturers are preempted under controlling Supreme Court and Sixth Circuit law. (R&R, ECF No. 1500, at 14–15). The Report also acknowledges the commonly understood fact "that, by the nature of the business model of a generic manufacturer, [the Generic Manufacturers] did not market or promote the opioids that they sold." (*Id.* at 15); *see also New York v. Actavis, PLC*, No. 14-CIV-7473, 2014 WL 7015198, at *27 (S.D.N.Y. Dec. 11, 2014), *aff'd sub nom. New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638 (2d Cir. 2015) (recognizing and applying principle).

Nonetheless, the Report recommends denying the Motion on the mistaken premise that Plaintiff can rely upon conclusory assertions about all Defendants and, thus, was not required to identify any specific false statement or act of diversion made by the Generic Manufacturers in Montana. (*See e.g.*, R&R at 15, 33). The Report's conclusion that such a basic "level of specificity" is not required (*id.* at 33) is wrong. It conflicts with well-settled pleading standards set by the Supreme Court in *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007) and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), as well as Rule 9(b).

[1] Mallinckrodt LLC, SpecGx LLC, and Teva Pharmaceuticals USA, Inc. ("Teva USA") also join these Objections to the extent Plaintiff's claims rest on allegations regarding their generic products. (*See e.g.*, First Amended Complaint ("FAC"), at ¶¶ 47–49, 76–78.)

The instant Motion presents an opportunity for the Court to address the MDL plaintiffs' efforts to impose liability on manufacturers for the sale of generic opioid medications. There is simply no basis in law for Plaintiff to extend its overreaching claims, based on allegations of false marketing, to the sale of generic opioid medications that (1) are not promoted in the ways alleged in the FAC and (2) are subject to a federally-imposed duty that prohibits generic manufacturers from providing risk disclosures that are different than those of their brand counterparts. The Court should not adopt the Report to the extent that it recommends denying the Generic Manufacturers' Motion, because Plaintiff has failed to allege sufficient facts to state a plausible claim in the FAC against the Generic Manufacturers.[2]

ARGUMENT

I. STANDARD OF REVIEW

On a dispositive motion, including a motion to dismiss, the district court's review of a magistrate judge's report and recommendation is *de novo*. *See* Fed. R. Civ. P. 72(b)(3) ("The district judge must determine *de novo* any part of the magistrate judge's disposition [of a dispositive motion] that has been properly objected to."); *Allen v. Int'l Truck & Engine Corp.*, No. 3:07CV361, 2010 WL 749655, at *2 (S.D. Ohio Feb. 26, 2010) ("Whenever it rules on objections to the report and recommendations of a Magistrate Judge on a dispositive motion, such as a motion to dismiss, the District Court must apply a *de novo* standard of review.").

To survive a motion to dismiss under Rule 12(b)(6), Plaintiff must allege factual allegations that transcend the "speculative," "conceivable," and "possible," and must "state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 555. It is beyond dispute that

[2] To avoid duplication, the Generic Manufacturers also adopt and incorporate herein the arguments made in the Objections asserted by the Brand Manufacturers to the Report ("Brand Manufacturers' Objections").

"[t]hreadbare recitals of the elements of a cause of action" and "mere conclusory statements" are insufficient. *Ashcroft*, 556 U.S. at 678. Moreover, because Plaintiff's claims rest on an alleged fraudulent campaign to market opioid medicines and a failure to report suspicious orders (FAC ¶¶ 4, 14, 326, 401), Plaintiff must satisfy Rule 9(b)'s particularity standard. *See Frank v. Dana Corp.*, 547 F.3d 564, 570 (6th Cir. 2008). To do so, Plaintiff must plead the "who, what, when, where, and how" of any alleged fraud, *Republic Bank & Tr. Co. v. Bear Stearns & Co.*, 683 F.3d 239, 256 (6th Cir. 2012), including "the time, place, and content of the alleged misrepresentations," the "fraudulent scheme," "fraudulent intent," and "injury resulting from the fraud." *Sanderson v. HCA-The Healthcare Co.*, 447 F.3d 873, 877 (6th Cir. 2006).

II. THE MAGISTRATE JUDGE ERRED IN FAILING TO DISMISS THE CLAIMS AGAINST THE GENERIC MANUFACTURERS.

The Report correctly concludes that Plaintiff's state-law marketing claims against the Generic Manufacturers based upon something other than affirmative false or misleading marketing are preempted by federal law. (R&R at 14–15); *see also PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011); *In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917 (6th Cir. 2014). The Report, nonetheless, errs in finding that Plaintiff has sufficiently alleged claims against the Generic Manufacturers based on: (a) affirmative false or misleading marketing; and (b) a failure to report possible diversion. (R&R at 15, 21, 33, 36.) These claims should be dismissed under *Iqbal*, *Twombly*, and Rule 9(b).

A. The Magistrate Judge Recognized That There Is No Specific Act Of False Or Misleading Marketing By The Generic Manufacturers, Yet Refused To Dismiss The Claims (Counts I And III-X).

Counts I and III-X are all based, in part, upon the allegedly false marketing of prescription opioids.[3] *See* Generic Manufs.' Mem. Supp. Mot. Dismiss, ECF No. 930, at 6. The Magistrate Judge recognized that Plaintiff's claims are "based on marketing misrepresentations." (R&R at 15; *see also id.* at 21 (acknowledging nuisance claim based on "deceptive promotion"), 33 ("deceptive marketing practices").) Plaintiff, therefore, must plead specific misstatements by each Generic Manufacturer—and must do so with the specificity required by Rule 9(b).

Plaintiff failed to do so. Plaintiff did not plead "'a single statement attributable to any of the Generic Manufacturers about one of their generic medicines; a single statement made by a Generic Manufacturer that reached a Montana doctor, a tribal citizen who received an opioid prescription, or Plaintiff itself, or any of the requisite details of any fraudulent conduct, such as who made an allegedly false statement, when, to whom, and why it is purportedly false . . . .'" (R&R at 33 (quoting Generic Manufacturers' briefing).) The Report acknowledges the absence of these basic details in the FAC. *Id.* Nonetheless, the Report mistakenly concludes that this "level of specificity is ***not required at the pleading stage*** where the complaint provides sufficient factual content for the court to reasonably infer that the Manufacturer Defendants [including the Generic Manufacturers] are liable." *Id.* at 33 (emphasis added). This conclusion is erroneous for multiple reasons.

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[3] (FAC ¶ 829 (RICO—Count I), ¶ 890 (federal common law public nuisance claim—Count III); ¶¶ 924, 929, 935, 940, 942 (state common-law public nuisance—Count IV), ¶¶ 964–65 (statutory public nuisance—Count V), ¶¶ 1052–54 (fraud claim—Count VII), ¶¶ 1071, 1081 (unjust enrichment—Count VIII), ¶¶ 1089–90, 1092 (civil conspiracy—Count IX), ¶¶ 1111–12 (statutory consumer protection claim—Count X).)

As an initial matter, the Report deviates from *Iqbal* and *Twombly*. Plaintiff cannot proceed on false marketing claims that do not identify specific acts of false or misleading marketing by the Generic Manufacturers—much less link such allegedly false or misleading statements to any prescription, patient, or harm in Montana. For example, while the Magistrate Judge cited Paragraphs 929–30 of the FAC in support of his recommendation (R&R at 33–34), these allegations are quintessential "conclusory statements" and "legal conclusions" that are insufficient under controlling law.[4] *Iqbal*, 556 U.S. at 678. They do not even pertain to the Generic Defendants in particular. *See, e.g.*, *See In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, 756 F.3d at 932 (affirming dismissal of false marketing claims against all "Generic Manufacturers" because plaintiffs failed to plead specific facts against each defendant to support legal theory).

This requirement of pleading an actual false or misleading misrepresentation ***by each of the Generic Manufacturers*** is particularly critical because, as the Supreme Court has made clear, the plausibility of Plaintiff's claims is "a ***context-specific task*** that requires the reviewing court to draw on its judicial experience and common sense." *Ashcroft*, 556 U.S. at 679 (emphasis added). It is well-settled that generic manufacturers "compete on price and avoid marketing to physicians because the costs of such marketing severely impact their ability to offer the significantly lower prices upon which they compete." *Actavis, PLC*, 2014 WL 7015198, at *27. This context must be considered in evaluating the plausibility of Plaintiff's false marketing

[4] (FAC ¶ 929 ("Defendants intentionally, unreasonably, negligently and/or unlawfully deceptively marketed and pushed as many opioids onto the market as possible . . . ."); *id.* at ¶ 930 ("Each Defendant is liable for creating the public nuisance because the intentional and unreasonable and/or unlawful and/or negligent conduct of each Defendant was, at the very least, a substantial factor in producing the public nuisance and harm to Plaintiff and Plaintiff's Community.").)

claims. Because generic manufacturers do not promote the safety or efficacy of their generic medicines, Plaintiff's conclusory assertions of false marketing against ***all Defendants*** are woefully insufficient to state a claim against Generic Manufacturers.

But even if Plaintiff's conclusory assertions were sufficient (and they are not), the Report ignores the plain language of Rule 9(b), which provides that "[i]n ***alleging*** fraud . . . , a party must state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b) (emphasis added). Rule 9(b) thus ***does*** require specificity at the pleading stage. The FAC does not come close to doing so. The FAC fails to allege a single statement attributable to any Generic Manufacturer about opioids—much less one that reached a Montana prescriber, one of Plaintiff's citizens, or the Plaintiff itself. The FAC thus also fails to plead the specific details of any such representation, such as who made it, when, to whom, and why it is purportedly false.

In reaching his recommendation, the Magistrate Judge appears to have relied on language from *Ohio Pub. Emps. Ret. Sys. v. Fed. Home Loan Mortg. Corp.*, 830 F.3d 376 (6th Cir. 2016) ("*OPERS*"), which is entirely inapposite. (*See* R&R at 33 (citing *OPERS*, 830 F.3d at 383).) *OPERS* was a securities fraud case against a single defendant. There, the district court held that the plaintiff's claims were subject to the heightened pleading standard of Rule 9(b) and then held, based on particularized allegations against a single defendant of that defendant's alleged misstatements, that the plaintiff had stated a claim. *OPERS*, 830 F.3d at 384–85, 388 (plaintiff alleged systemic mismanagement, based on defendant's financial reports and specific examples of policy violations, and specific misstatements). The Magistrate Judge failed to hold Plaintiff's claims to this same heightened pleading standard despite acknowledging that they all sound in fraud (*i.e.*, false or misleading marketing). (R&R at 15, 21, 33.)

Ignoring Rule 9(b), the Report eliminated Plaintiff's pleading burden as to the Generic Manufacturers by permitting Plaintiff to engage in multiple layers of group pleading, even though Generic Manufacturers are separate and distinct entities that do ***not*** engage in affirmative marketing as to the safety and efficacy of their opioid medicines. (*See e.g.* R&R at 15 (finding "allegations against all manufacturers" to be sufficient as to Generic Manufacturers); *id.* at 33 (finding "allegations against Manufacturer Defendants" to be sufficient as to Generic Manufacturers).) For instance, the FAC lumps together the three Actavis Generic Entities together with five other corporate entities (owned by a different company) under the fictitious "Actavis" name (FAC ¶ 45); the FAC then makes allegations against these fictitious entities. (FAC ¶¶ 193–96, 276, 313, 520–21, 554, 557.) Worse yet, the FAC lumps together all the Generic Manufacturers with other unrelated opioid manufacturers as "Marketing Defendants," making hundreds of allegations using the name of this undifferentiated entity, despite pleading no facts showing the Generic Manufacturers engaged in any type of "marketing." (*E.g.* FAC ¶¶ 15–23, 110, 111, 115, 120, 133, 144–51, 201–02, 209–11, 221, 224–25, 226, 236, 237, 254–55, 263, 276, 316, 319–24, 332, 342, 344, 350.) And as a third layer of improper group pleading, the FAC lumps the Generic Manufacturers in with more than 12 separate distributors and pharmacies, making conclusory assertions against all "Defendants" collectively. (*E.g.* FAC ¶¶ 15–23.) Under Sixth Circuit law, group pleading is improper to state a claim against generic manufacturers. *In re Darvocet, Darvon, and Propoxyphene Prods. Liab. Litig.*, 756 F.3d at 932 (lumping various generic manufacturers together was improper and failed to state claim).

This case is analogous to *Hoover v. Langston Equip. Assocs., Inc.*, in which the Sixth Circuit affirmed the dismissal of a complaint under Rule 9(b) because of the same type of rampant group pleading found here. The Court of Appeals held:

> The district court did not err in its alternative ground for dismissing Count One pursuant to Rule 9(b), that plaintiffs had not alleged with specificity who had made particular misrepresentations and when they were made but rather plaintiffs had articulated general averments of fraud attributed to 'the defendants.' The complaint . . . alleges misrepresentations without sufficiently identifying which defendants made them. The complaint does not enable a particular defendant to determine with what it is charged.

958 F.2d 742, 745 (6th Cir. 1992). Likewise, here, Plaintiff's generalized allegations grouping all "Defendants" and "Manufacturer Defendants" together are insufficient to put any of the Generic Manufacturers—which are separate and independent entities—on notice of the particular affirmative misrepresentations that it supposedly made in Montana. (*See* R&R at 34.) Accordingly, the Court should sustain the Objections and grant the Generic Manufactures' Motion.

B. Plaintiff's Claims (Counts II-X) Against The Generic Manufacturers Based Upon A Failure To Prevent Diversion Also Fail.

Plaintiff's claims based upon the purported failure to prevent diversion fail for the same reason. Without citing a single allegation against any of the Generic Manufacturers, the Magistrate Judge found that Plaintiff made sufficient allegations that "Defendants" failed to comply with their suspicious order monitoring obligations. (*See* R&R at 9, 30–31, 33.) But such allegations fail to state claims against any Generic Manufacturers under *Iqbal* and *Twombly*.

The FAC contains no "factual content" to show that any Generic Manufacturer disregarded its suspicious order monitoring responsibilities. (*See* Generic Manufs.' Mem. Supp. Mot. Dismiss, ECF No. 930-1, at 13.) The FAC does not allege a single suspicious order that any Generic Manufacturer failed to report, a single misleading statement or omission by any Generic Manufacturer regarding its reporting obligations, or how any alleged failure to report by any Generic Manufacturer caused harm to Plaintiff. Since the FAC does not contain such detail, it is no surprise that no such allegations are identified in the Report. Instead, the Report

identifies nothing more than generalized allegations that "Defendants"— which Plaintiff broadly defines to include numerous separate and independent brand manufacturers, distributors, and pharmacies—disregarded their regulatory obligations to monitor suspicious orders. (*See* R&R at 9, 30–31, 33.) These allegations amount to the type of "conclusory statements" and "threadbare recitals of a cause of action's elements" that do not suffice to state a claim. *Iqbal*, 556 U.S. at 678. As a result, the Court should reject the Report and dismiss all of Plaintiff's claims against the Generic Manufacturers based upon a purported failure to prevent diversion.

C. The Report Errs As A Matter Of Law In Several Other Ways.

The Report errs as a matter of law for the additional reasons set forth in the Brand Manufacturers' Objections. First, Plaintiff cannot proceed on a products-based public nuisance claim under Montana or Oklahoma law. (Brand Mfgr's Objections, at § I.) Second, Plaintiff cannot recover compact funds used to provide health care under federal law. (*Id.* at § II.) Third, Plaintiff cannot recover public service costs under Oklahoma or Montana law under the common-law free public services doctrine. (*Id.* at § III.) Lastly, Plaintiff cannot satisfy the remaining core components of their claims. (*Id.* at § IV.)

CONCLUSION

There is simply no basis for the claims against the Generic Manufacturers, including false marketing claims based upon opioid medicines that the Generic Manufacturers do not promote and that are subject to a federal duty prohibiting warnings and disclosures beyond those accompanying their brand counterparts. Indeed, neither the Report nor the FAC identifies a single false or misleading statement—or any other act of misconduct—made by any Generic Manufacturer in Montana or elsewhere. Accordingly, the Court should sustain the objections raised above and grant the Generic Manufacturers' Motion.

April 29, 2019

Respectfully submitted,

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LOCAL RULE 7.1(F) CERTIFICATION

Pursuant to Local Rule 7.1(f), I hereby certify that this Court has ordered that length limitations applicable to complex cases apply to this matter, ECF No. 232 at 4 (No. 1:17-MD-2804), and that the foregoing brief complies with the 15-page limit imposed by this Court's October 10, 2018 Order, ECF No. 1032.

Dated: April 29, 2019

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CERTIFICATE OF SERVICE

I hereby certify that on April 29, 2019, a copy of the foregoing Partial Objection of the Generic Manufacturers to the Report and Recommendation of the Magistrate Judge on Their Motion to Dismiss was filed electronically in MDL Master Docket No. 17-md-2804 and in No. 1:18-op-45749-DAP. Notice of this filing was sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

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